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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,632	04/09/2004	Donn P. Cummings	DEKA:351US	9022

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FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER

BUI, PHUONG T

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/821,632	Applicant(s) CUMMINGS, DONN P.	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's amendment filed December 15, 2005. Claim 1-24 are pending and are examined in the instant application. This action is made FINAL. All rejections not set forth below have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, 2nd paragraph

2. Claims 1-24 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The ATCC Accession Number must be filled in where appropriate to clearly provide the identifying characteristics for Applicant's corn variety designation. Compliance with this requirement may be held in abeyance until allowability is indicated.

In claims 16 and 21, "yield enhancement", "improved nutritional quality", "decreased phytate content", "modified fatty acid metabolism" and "modified carbohydrate metabolism" and "restoration of male sterility" are not traits. Furthermore, they lack a comparative basis. It is noted that "yield enhancement" and "improved nutritional quality" have been deleted from claim 21. Applicant traverses that these terms are well known in the art, defined by the specification and do not lack a comparative basis because these traits are conferred by a transgene or conversion. Applicant's traversals are unpersuasive because it appears that Applicant is using "traits" and "genes" interchangeably, however, they are not synonymous. For example,

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a gene encodes a *Bt* protein and the trait is insect resistance, and not *vice versa*. Moreover, these terms are not defined by the specification and while they may be commonly used in the art, they are not definite because one skilled in the art would define these terms differently from another skilled in the art. With regard to lack of comparative basis, inserting "as compared to a plant lacking the transgene" would obviate this portion of the rejection.

In claim 19, the metes and bounds of "both alleles at substantially all of the loci consist essentially of the allele" are unclear. Furthermore, it is unclear whether "consist essentially of" in claims 19 and 23 means the number of alleles at the same locus may vary or that the allele itself can have structural differences. Applicant traverses, stating that both loci are the same as the corresponding loci in the deposited variety, and "consist essentially of" modifies "allele". Applicant's traversals are unpersuasive because Applicant's traversals are not commensurate in scope with the claims: the claim language is "substantially all" loci, which is not the same as all loci as argued by Applicant. With regard to "consist essentially of", Applicant's response that ""consist essentially of" modifies "allele"" does not answer the question presented and thus the rejection is maintained. The use of "substantially all" in combination with "consist essentially of" renders this claim vague and indefinite, and leaves one to wonder as to what exactly is present at each locus.

Accordingly, this rejection is being maintained.

Claim Rejections - 35 USC § 112, 1st paragraph, deposit

3. Claims 1-24 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record. Applicant indicated that a deposit complying with 37 CFR 1.801-1.809 will be made. Accordingly, compliance with the deposit requirement may be held in abeyance until the application is otherwise in condition for an allowance.

Claim Rejections - 35 USC § 112, 1st paragraph, written description

4. Claims 3, 18 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines. Claim 3 is included because Applicant indicated that "a plant part" would include a hybrid seed (p. 7 of Applicant's response filed December 15, 2005). The rejection of record is as follows:

"The claims are drawn to hybrid corn plants having undisclosed identifying characteristics whereby only one parent in the first cross is known, and none of the characteristics of the second parent are known. The claims are also drawn to a method of producing an inbred corn plant derived from corn variety I082216 by crossing a progeny plant for 3-11 generations, each time with an unknown parent.

Applicant should note that no identifying characteristics are set forth for the claimed hybrid F1 progeny. Further, no identifying characteristics are set forth for the second parent. Applicant does not indicate that the claimed F1 progeny

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would have all of physiological and morphological characteristics of the I082216 parent. While Table 2 sets forth the traits for a hybrid, the claims are not limited to this particular hybrid by its hybrid designation or by any particular traits. Different hybrids would have different traits, depending on what the genetic makeup of the second parent is. Other hybrids may have traits which are vastly different from the traits in these tables. Thus, F1 progeny plants which are not claimed by any identifying characteristics are not considered to be possessed by Applicant, and one skilled in the art would not be able to predictably determine whether or not a particular corn plant is encompassed by the claims.

A method of producing an inbred corn plant derived from I082216 by outcrossing with a non-I082216 parent for 3-11 generations lacks adequate written description because only one parent from the first cross is known, and none of the parents of any of the subsequent crosses is known. No selection for any particular morphological or physiological trait is indicated for the progeny plants obtained at any generation level. If the claimed F1 plant itself cannot be identified by characteristics clearly disclosed in the specification, then it is not even possible to determine whether a plant of unknown parentage is or is not covered by the claim. There is insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genomic structure or phenotypic characteristics of the plant obtained at each level of crossing or at each generation, absent further guidance. Over multiple generations, such as 3-11 generations as claimed here, the identifying characteristics for each generation become highly unpredictable, especially in view of the fact that none of the identifying characteristics of the progeny plants are disclosed in the specification or set forth in the claims. Additionally, neither the starting materials nor the end product is adequately described. Applicant should note that methods which generate F1 are adequately described because the F0 parent is adequately described, and crossing an F0 parent with another parent to select for particular traits or characteristics in the F1 progeny plants is routine in the art. However, in methods to generate F2 and subsequent generations, no traits or characteristics are disclosed for the F1 parent, as indicated above. The disclosure of F1 traits is essential to the claimed invention since the F1 parent is required to generate F2 progeny plants. Thus, these methods would involve crossing two parents having unknown characteristics to generate F2 progeny plants having unknown characteristics. Thus, absent any disclosure of what the starting materials are for each of the crosses, one skilled in the art cannot predictably determine what plants should be used for each cross and what identifiable plants are obtained upon completion of the claimed method.

Accordingly, there is a lack of adequate description for the claimed hybrid progeny plants and method of using the deposited plant material in multiple crosses to introduce undisclosed genes or traits. In view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the

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disclosure that Applicant was in possession of the claimed invention at the time of filing. Thus, for the reasons set forth above, the claimed invention lacks adequate written description under current written description guidelines (see Written Description Requirement published in Federal Register/ Vol. 66, No. 4/ Friday, January 5, 2001/ Notices; p. 1099-1111)."

Applicant traverses that these issues have been considered and reversed by the Board in similar corn applications, F1 plants will have half of their genetic material from the deposited variety, the second parent that is used to make the claimed hybrid is irrelevant, only the starting material is required to practice the claimed methods, and corn breeding is well known to those skilled in the art.

Applicant's traversals are unpersuasive for the following reasons. The Board's decisions are unpublished and therefore do not serve as precedent for the instant application. Further, every application is decided on its own merits. Applicant does not claim the F1 hybrid disclosed but claim any hybrid using I082216 as one parent in the first cross. Applicant does not make a deposit for the claimed F1 hybrid. Applicant does not require that any of the traits from the deposit seed be retained in the F1 hybrid. It cannot be said that an F1 hybrid is adequately described because one of its parent is adequately described, because the unknown second parent also contributes to the genetic material of the F1 hybrid and may in fact mask the traits of the other parent. Both parents are relevant to the claimed invention. While one skilled in the art can readily determine whether or not a particular corn plant is Applicant's deposited variety—because the parent is deposited and adequately described, one would not be able to make the same determination for the claimed F1 progeny—because the hybrid has not been deposited or described at all. The non-described portion of the hybrid

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plant is critical if its expression masks recessive traits of the deposited parent. This position is consistent with current Office practice because patented hybrid corn claims recite both inbred parents which have been deposited (for example, see USPN 6989479 (A), claims 19 and 20). Since the method requires F1 and progenies of F1 to at least 11 generations, these methods are not adequately described because the products necessary for each step have not been described or selected for. Description of the starting material alone is insufficient when materials necessary for subsequent steps are not adequately described. While corn breeding is well known to those skilled in the art, those skilled in the art also recognize the necessity of know the traits of both parents in any cross in order to select for progeny plants having the desired combination of traits.

Accordingly, for the reasons set forth above, the claimed invention lacks adequate written description.

Claim Rejections - 35 USC § 112, enablement

5. Claims 18-22 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods which involve one outcrossing to introduce a particular trait and 3-10 backcrossings to the deposited parent such that the resulting progeny plant contains the desired trait and all the physiological and morphological characteristics of the deposited variety, does not reasonably provide enablement for methods which involve multiple outcrossings or methods which do not select for an identifiable trait. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use

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the invention commensurate in scope with these claims. The rejection of record is as follows:

“Claim 18 is directed to a method of producing an inbred corn plant. However, the method steps encompass outcrossings with genetically distinct parents which would not result in an inbred corn plant but rather a hybrid corn plant. Since Applicant provided no working examples of any inbred plants produced by the method of claim 18, and the art does not recognize that 3-11 generations of outcrossings would result in an inbred plant, Applicant has not enabled the claimed invention as commensurate in scope with the claims.

With regard to claims 19-22, these methods are not enabled because neither Applicant's disclosure nor the state of the prior art recognizes that two backcrosses is sufficient to produce a converted corn plant containing a new trait not present in the I082216 variety. Murray et al. (Proceedings of the 43rd Annual Corn and Sorghum Research Conference, Vol. 43, pp.72-87, 1988) teaches the failure to obtain any variety-specific molecular markers in six different inbreds (p79); and linkage drag in corn results in 10% rather than 1% of the donor parent genome following ten backcrosses. Thus, it is unpredictable that the method set forth in these claims would result in a corn plant having all of the physiological and morphological traits of I082216 and one additional trait following two backcrosses. Applicant provided no guidance as to how the problems set forth by Murray could be overcome. The claims are not limited to any particular trait that can be reliably and predictably introduced into the I082216 variety without additional undesirable traits from the donor parent. Applicant provided no working example of a conversion corn plant having a new trait by the claimed method. Accordingly, Applicant has not enabled the claimed invention as commensurate in scope with the claims.”

Applicant traverses that the specification includes a working example describing a conversion that was made with a proprietary corn variety, cited art Murray performed six backcrosses, and RFLP and SSR loci information available since Murray would allow for elimination of the linkage drag problem discussed in Murray.

Applicant's traversals are unpersuasive because Applicant's arguments are not commensurate in scope with the claims. Claim 18 is directed to a method of producing **inbred** corn by **outcrossing** with a genetically different parent for 3-11 generations.

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Since the art to date does not recognize how this can be done, and Applicant has provided no working example or guidance as to how this can be done, the claimed invention is not enabled as commensurate in scope with the claims. With regard to claims 19-22, again, Applicant's arguments are not commensurate in scope with the claimed invention. The method recites **two** backcrosses, which is not equivalent to Murray's six backcrosses. Furthermore, RFLP and SSR loci information only indicates what the resulting genetic makeup of the new progeny plant is and does not provide guidance as to how a new trait can be introduced into an existing plant while retaining all the morphological and physiological characteristics it previously had. In fact, RFLP and SSR loci information may show that either the new trait has not been successfully introduced after two backcrosses or that the resulting plant lost many of the morphological and physiological characteristics of I082216 after two backcrosses.

Accordingly, for these reasons, Applicant has not enabled the claimed invention as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102 and 35 USC § 103

6. Claims 23-24 remain rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al. (US Pat. No. 5880342). The rejection of record is as follows:

"The prior art teaches a corn plant which shares some of the traits of I082216, including leaf, glume, fresh and dry husk and endosperm color. While the corn variety of the prior art has a different variety designation from the corn variety of the instant application, there are insufficient identifying characteristics set forth in the claims to distinguish the claimed plants from those of the prior art. At the F1 progeny level, no identifying characteristics are recited to distinguish Applicant's F1 plants from that of the prior art. The claims do not specifically recite a plant whereby all of the physiological and morphological characteristics of the I082216

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parent are retained. The method used to produce the claimed plants involves crossing I082216 with an unknown parent, and not all of the distinguishing characteristics of the I082216 parent are necessarily retained. None of the identifying features which distinguish Applicant's plants from those of the prior art are claimed. The method of producing the plant, namely using I082216 as the one parent, would not confer a unique property to the resultant corn which would distinguish it from the prior art plant. Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of the prior art. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. Since the Patent Office does not have the facilities to examine and compare the plant of Applicant's with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See *In re Best*, 562F.2d 1252, 195 USPQ 430 (CCPA 1977). Accordingly, the claimed invention is anticipated by or is rendered obvious in view of the prior art."

Applicant traverses that the claimed plants necessarily include half of the genome of the parent plant and hypothetical possibilities do not suffice.

Applicant's traversals are unpersuasive for the following reasons. Applicant does not disclose the genomic structure of the claimed hybrid. Applicant has made no deposit of the claimed hybrid. Applicant is silent as to what traits the claimed plant would possess. Only certain traits of the parent plant are identified—none of which are necessarily retained in the claimed progeny plants. Therefore, the claimed hybrid is not any one particular plant but encompasses a population of plants having various combinations of traits, one of the claimed combinations is represented by the plant of the prior art. Furthermore, since the Patent Office does not have the facilities to examine and compare the plant of Applicant's with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art.

Conclusion

7. No claim is allowed.
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communications from the Examiner should be directed to Phuong Bui, whose telephone number 571-272-0793.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975.

The fax phone number for the organization where this application or proceeding is assigned, for sending official correspondence, is 571-273-8300.

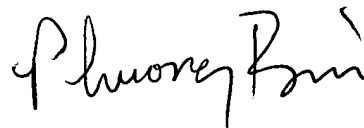
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Phuong T. Bui
Primary Examiner
Art Unit 1638

01/25/06